IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, v. GLEN MULREADY, in his official capacity as Insurance Commissioner of Oklahoma, and the OKLAHOMA INSURANCE DEPARTMENT, Defendants.	)	Civil Action No. CIV-19-977-J

OPENING MEMORANDUM IN SUPPORT OF
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION[1]

[1] All statements made or offered by Pharmaceutical Care Management Association ("PCMA") are solely the statements of PCMA and only the express statements, if any, of its members may be attributed to its individual members

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutory Authorities

Rules and Regulations

Additional Authorities

Oklahoma's Patient's Right to Pharmacy Choice Act ("Act") violates the Supremacy Clause. The Act restricts the ability of pharmacy benefit managers ("PBMs") to deliver lower drug prices and high quality pharmacy benefit management services to health plans covered by the Employee Retirement Income Security Act ("ERISA") and Medicare Part D and their beneficiaries. These federal statutes expressly preempt state laws that have a connection with, or act with respect to, ERISA and Part D plans. For this reason, the Act is preempted.

The Act and its implementing emergency regulations ("Regulations") took effect in November, 2019, and defendants Glen Mulready and the Oklahoma Insurance Department ("OID") have now decided to enforce them.[2] But enforcement of the Act and Regulations – which also are preempted and violate Oklahoma's Administrative Procedures Act ("APA") – will irreparably harm PBMs by subjecting them to state regulation in an area of broad federal preemption, requiring them to restructure their business models, and imposing on them unrecoverable financial and administrative costs, all of which are exacerbated by the COVID-19 crisis. This harm outweighs any interest the defendants might have in enforcing a statute preempted by federal law. Enforcement would also harm the public by diverting PBMs' resources away from responding to the pandemic and toward complying with a law that will increase the cost of prescription

[2] On November 5, 2019, the parties entered a stipulation in which the defendants agreed to stay enforcement pending a final order from this court. *See* Dkt. 19. The defendants expressed their intent to withdraw from the stipulation on April 7, 2020. *See* Dkt. 27.

drugs in Oklahoma – at a time when people can least afford such increases. The court should enjoin the defendants from enforcing the Act and Regulations.

STATEMENT OF FACTS

A. PCMA and the PBM Market

Plaintiff Pharmaceutical Care Management Association ("PCMA") is the national trade organization representing sixteen PBMs. PCMA's members manage prescription drug benefits for their customers: health plans including ERISA-covered employee benefit plans, Medicare Part D plans, and commercial health insurance plans across the country. Ex. 1: Declaration of Kim A. Caldwell ("Caldwell") ¶ 32. Many plans operate in multiple states, including Oklahoma. *Id*. ¶ 35; Ex. 2: Declaration of Adam Stacy ("Stacy") ¶¶ 2, 4; Ex. 3: Declaration of Brian Correia ("Correia") ¶¶ 2, 7; Ex. 4: Declaration of Mari Conlin ("Conlin") ¶¶ 2, 6; Ex. 5: Declaration of James R. Johnson ("Johnson") ¶¶ 1, 5.

When a health plan beneficiary– a worker, their family member, or a senior – fills a prescription, the transaction results from pre-existing contracts among at least five key players: pharmacies (or pharmacy services administrative organizations – "PSAOs" – working on their behalf), wholesalers, manufacturers, PBMs, and health plans. Pharmacies purchase drugs from wholesalers, who, in turn, purchase drugs from manufacturers. Pharmacies then dispense those drugs to beneficiaries of health plans serviced by PBMs, and the pharmacy is reimbursed by the PBM or beneficiary or some combination thereof. Caldwell ¶¶ 23-32. Some prescription drug benefit plans include

cost-sharing, such as co-insurance or a deductible, where the beneficiary pays a price that is some portion of the price charged to the health plan, by the pharmacy, through the PBM. *Id* ¶ 48.

B. PBMs' Core Services

The PBM business model includes several core services, at least four of which are affected by the Act. First, PBMs contract with retail pharmacies across the country to create pharmacy networks on health plans' behalf. Networks are groups of pharmacies that agree to fill beneficiaries' prescriptions using their pharmacy benefits. Caldwell ¶ 31. In exchange for network membership, pharmacies agree to accept certain reimbursements from plans and cost-sharing from beneficiaries. *Id.* ¶¶ 38, 41. PBMs contract to create various networks to offer their customers many plan design options. For example, open networks have large numbers of pharmacies that generally require higher copays and reimbursements. Preferred networks have fewer pharmacies, but beneficiaries filling prescriptions at those pharmacies will pay lower or fewer copays, and plans will generally pay lower reimbursements (which also results in lower cost-sharing for beneficiaries). *Id*. ¶¶ 41-42; Conlin ¶ 14. Preferred pharmacies agree to these lower reimbursements in exchange for higher sales volumes, which PBMs incentivize by offering those discounts. Caldwell ¶ 42; Conlin ¶ 15. Generally, health plan beneficiaries have access to the same pharmacy networks regardless of their home state. Caldwell ¶ 35.

Second, PBMs offer disease management and medication adherence programs, including for beneficiaries who suffer from complex, chronic, or rare diseases requiring

specialty drugs. Specialty pharmacies staffed by highly skilled and experienced pharmacists are a critical tool for these disease management services, because such pharmacies support patients in many ways beyond dispensing drugs. *Id*. ¶ 45. Specialty pharmacies are frequently mail-order pharmacies. *Id*.

Third, PBMs process beneficiaries' prescription drug claims in real-time and at the point of sale using technology and proprietary drug pricing formulas to support prescription reimbursement claims and fulfillment. *Id*. ¶ 46; Conlin ¶ 17. PBMs may reduce the payment on a claim post-adjudication if there was an error or based on the pharmacy's failure to meet certain performance standards, such as patient adherence goals. Caldwell ¶ 49.

Fourth, PBMs perform customer service functions for beneficiaries. These include informing them about their benefits and where they can obtain them.

PBMs can perform each function in different ways, tailored to health plans' and beneficiaries' needs. Their unique services differentiate PBMs and make their services valuable. *See, e.g.*, Conlin ¶ 13.

C. Prescription Drug Benefits in Oklahoma

PBM customers include self- and fully-insured health plans covering beneficiaries who reside or buy drugs in Oklahoma. Of 3.9 million residents, about 3.4 million

Oklahomans are covered by public or private insurance.[3] Approximately 1.7 million have employment-based health benefit plans.[4] In addition, over 500,000 Oklahomans, mostly seniors, receive prescription drug benefits through the Medicare program.[5]

D. The Act and Regulations

The Act regulates PBMs and health insurers, and has several key impacts. Overall, it restricts PBMs' networks and PBMs' claims processing functions in a manner that will increase the cost of prescription drug coverage and leave health plans with fewer choices for designing that coverage. The Regulations magnify the Act's effects, and provide that the Act applies to specialty drugs.

1. The Act's "Network Restrictions"

- Each standard and preferred pharmacy network must be designed so that a certain percentage of network beneficiaries lives within a set geographical distance from at least one network pharmacy. *Retail pharmacies*, but not mail-order pharmacies, count toward these *access standards*. 36 O.S. § 6961(A)-(B) (the "Retail-Only Pharmacy Access Standards").

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[3] Kaiser Family Foundation, "Health Insurance Coverage of Nondelderly 0-64," https://www.kff.org/other/state-indicator/nonelderly-0-64/?dataView=1&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last accessed May 12, 2020).

[4] *Id*.

[5] Centers for Medicare and Medicaid Services, "Monthly Enrollment by State," https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-State.html (last accessed May 12, 2020).

- PBMs must allow *any willing pharmacy* to participate in the PBM's preferred network if that pharmacy agrees to that network's terms and conditions. 36 O.S. § 6962(B)(4) (the "Any Willing Provider Provision").
- PBMs may not *deny, limit, or terminate pharmacy* contracts because a pharmacist employed by the pharmacy is on probation with the State Board of Pharmacy. 36 O.S. § 6962(B)(5) (the "Probation-Based Pharmacy Limitation Prohibition").
- The three "Beneficiary Direction Provisions," restrict PBMs from directing beneficiaries to certain pharmacies:
    - PBMs may not require beneficiaries to use pharmacies directly or indirectly owned by the PBM (*i.e.*, an *affiliated pharmacy*). 36 O.S. § 6961(C) ("Affiliated Pharmacy Requirement Prohibition").
    - If a PBM lists one pharmacy on *promotional materials*, then it must list all pharmacies "participating in the preferred and nonpreferred pharmacy and health networks." 36 O.S. § 6961(D) (the "Promotional Materials Provision").
    - PBMs may not give *beneficiaries incentives*, such as discounts, to buy drugs at particular pharmacies. 36 O.S. § 6963(E) (the "Beneficiary Incentive Prohibition").

2. The Act's "Claims Processing Provisions"

- PBMs may not charge pharmacies *service fees* relating to the adjudication of a claim. 36 O.S. § 6962(B)(2) (the "Service Fee Prohibition").
- The reimbursements PBMs pay to un-affiliated pharmacies must *match* those it pays to *affiliated pharmacies* on a unit-to-unit basis. 36 O.S. § 6962(B)(3) (the "Affiliated Pharmacy Price Match").
- PBMs may not, *post-sale*, *reduce the price* paid to a pharmacy for a covered claim, or deny reimbursement, except in cases of fraud, or errors uncovered in an audit. 36 O.S. § 6962(B)(6) (the "Post-Sale Price Reduction Prohibition").
- PBMs must *pay terminated network pharmacies* outstanding claims upon termination. 36 O.S. § 6962(B)(7) (the "Termination Payment Requirement").

3. The Act's "Health Insurer Obligations"

- *Health insurers must monitor* all activities carried out by, or on behalf of, the health insurer under the Act, and those with whom the health insurer contracts. 36 O.S. § 6963(A)-(B) (the "Health Insurer Monitoring Requirement").

4. The Regulations

- Health insurers must *approve all contracts* used by its contracted PBMs and retail pharmacy networks to ensure compliance with the Act. Okla. Admin. Code § 365:25-29-9(c)(1) (the "Contract Approval Rule").
- The Act applies to *specialty drugs*. Okla. Admin. Code § 365:25-29-7.1(a)(2) (the "Specialty Drug Rule").

- If PBMs list one pharmacy on its *promotional material*, then it must list all pharmacies on that material. Okla. Admin. Code § 365:25-29-7.1(a)(3) (the "Promotional Materials Rule").

E. The Act's and Regulations' Impact on PBMs

1. The Act and Regulations Limit PBMs' Abilities to Lower Prices and Offer Varied and Nationally Uniform Benefit Design

PBMs currently have several methods for lowering costs and offering varied plan design. The Act limits PBMs' ability to use these methods. First, the Network Restrictions weaken PBMs' ability to offer sales volume to preferred pharmacies in exchange for lower costs. The Any Willing Provider Provision opens up preferred networks to more pharmacies, and the Beneficiary Direction Provisions prevents PBMs from incentivizing plan beneficiaries to use given pharmacies. Caldwell ¶ 55. Together, these provisions undo the purpose of preferred networks (offering high-quality, lower cost prescription drug benefits from a limited number of pharmacies). *Id*.

Second, PCMA reads the Act, combined with the Specialty Drug Rule, to prevent PBMs from offering disease management services through restricted networks of specialty pharmacies. Specialty-only networks are limited to pharmacies experienced in providing drugs that require special handling; maintain adequate inventory of high-cost specialty medication to ensure timely dispensing; and offer coordination of care for individuals with complex, chronic, and/or rare diseases that can result in better outcomes and long-term savings. *Id*. ¶ 45; Conlin ¶ 42. Yet, the Emergency Rule appears to apply

the Retail-Only Pharmacy Access Standards to specialty networks, making them impossible to maintain because specialty pharmacies are typically mail order only. Caldwell ¶ 45. Thus, PBMs will no longer be able to offer these services to health plans with beneficiaries needing specialty drugs and cost-effective management.

Third, the Claims Adjustment Prohibitions prevent PBMs from using their standard drug reimbursement processes, including reducing reimbursement post-processing, and recouping the costs of their services. *Id*. ¶¶ 59-60.

2. The Act and Regulations Impede PBMs' Abilities to Ensure Network Quality

PBMs ensure quality pharmacy service in several ways impeded by the Act and Regulations, including by requiring quality standards in pharmacy network contracts, and encouraging beneficiaries that need specialty drugs to go to specialty pharmacies. Caldwell ¶ 7. As described above, the Network Restrictions limit PBMs' abilities to offer volume in exchange for favorable contractual terms, including quality standards. The Act and Regulations also weaken PBMs' abilities to direct beneficiaries to specialty pharmacies for high-quality disease management services. *Id*. ¶ 62.

As well, the Act prevents PBMs from terminating or limiting the contracts of pharmacies whose employees have been sanctioned by the Oklahoma Board of Pharmacy, prohibits them from imposing qualitative performance standards using post-sale price concessions, and prevents them from tailoring written communications with beneficiaries concerning specific pharmacies. *Id*. ¶¶ 59, 63, 67**.**

3. The Act and Regulations Impose Oklahoma-Specific Requirements on Nationwide Companies

PBMs offer uniform services to plans with beneficiaries without regard to state lines. Since beneficiaries from other states fill prescriptions in Oklahoma, their benefits will change when they cross state lines. For example, if they were able to access preferred network pricing in their home state, they would not be able to access it in Oklahoma. Caldwell ¶ 57.

4. Complying with the Act and Regulations Will Impose Administrative and Financial Burdens on PBMs

Complying with the Act will require PBMs to renegotiate contracts with health plans and pharmacies. Doing so will impose administrative burdens on PBMs. Caldwell ¶ 56. In addition, because the Act is Oklahoma-specific, the Act will subject PBMs to the ongoing burden of having to simultaneously comply with Oklahoma and non-Oklahoma regimes. Conlin ¶ 49; Correia ¶ 45; Johnson ¶ 40; Stacy ¶ 23.

The Act will also cost PBMs financially because it limits PBM revenue sources by prohibiting post-case price concessions and pharmacy service fees. Caldwell ¶¶ 59-60. It also imposes costs, including by requiring PBMs to redesign and reprint beneficiary communications. *Id*. ¶ 67.

STANDARD FOR PRELIMINARY INJUNCTION

A party seeking a preliminary injunction must show: "(1) the movant is substantially likely to succeed on the merits; (2) the movant will suffer irreparable injury if the injunction is denied; (3) the movant's threatened injury outweighs the injury the

opposing party will suffer under the injunction; and (4) the injunction would not be adverse to the public interest." *First Western Capital Mgmt. v. Malamed,* 874 F.3d 1136, 1141 (10th Cir. 2017) (citation omitted). A movant that seeks a preliminary injunction that maintains the status quo bears a lesser burden than one who seeks to disrupt that status quo. *See, e.g.*, *Awad v. Ziriax*, 670 F.3d 1111, 1125 (10th Cir. 2012).

PCMA satisfies the requirements for a preliminary injunction. In addition, a preliminary injunction will maintain the status quo of non-enforcement of the Act and Regulations. Thus, this Court should preliminarily enjoin Defendants from enforcing the Act and Regulations.

ARGUMENT

A. PCMA is Likely to Succeed on the Merits

PCMA is likely to succeed on the merits because the Act and Regulations are preempted by ERISA and Medicare Part D and the Regulations violate the APA.

1. ERISA Preempts the Act and Regulations

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plans." 29 U.S.C. § 1144(a). A state law "relates to" an employee benefit plan "if it has a connection with . . . such a plan." *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 90 (1983). A law has a "connection with" a plan if it interferes

with nationally uniform plan administration or governs a central matter of plan administration. *Gobeille v. Liberty Mut. Ins. Co*., 136 S. Ct. 936, 943 (2016).

ERISA preemption is broad, and does not require any conflict between the state law at issue and ERISA's substantive terms. *See Metro. Life Ins. Co. v. Mass*., 471 U.S. 724, 737 (1985) ("ERISA's broad pre-emption provision was intended to pre-empt any state law that '[related] to' an employee-benefit plan, not merely those state laws that directly conflicted with a substantive provision in the federal statute."). It also applies to laws that "only indirectly affect ERISA plans." *Fuller v. Norton*, 86 F.3d 1016, 1020 (10th Cir. 1996).

ERISA preempts PBM-regulating laws. In *Gobeille*, the Supreme Court held that ERISA preempts laws that apply to third-party administrators. *See Gobeille*, 136 S. Ct. at 941-42. Courts both before and after *Gobeille* have held that this applies to PBMs. *See Pharm. Care Mgmt. Ass'n v. District of Columbia*, 613 F.3d 179, 185-86 (D.C. Cir. 2010); *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1112-13 (8th Cir. 2018) (*cert* granted, 140 S. Ct. 812, argument pending).

For several reasons, the Act and Regulations interfere with nationally uniform plan administration by creating a "patchwork scheme of regulation." *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 11 (1987). The Network Restrictions require PBMs to structure networks, and provide disease management services, differently in Oklahoma than elsewhere. The Network Restrictions and Affiliated Pharmacy Price Match require PBMs to change their pricing methodologies in Oklahoma. Finally, the Promotional Material

Provision and Rule impermissibly require PBMs to make Oklahoma-specific versions of any material that mentions any provider. ERISA expressly describes the information plans must provide their members, such as summary plan descriptions. *See* 29 U.S.C. § 1024(b). Thus, the Tenth Circuit has held that ERISA preempts state laws requiring disclosures to beneficiaries. *David P. Coldesina, D.D.S., P.C., Empl. Profit Sharing Plan & Trust v. Estate of Simper*, 407 F.3d 1126, 1136 (10th Cir. 2005).

The Act also interferes with central matters of plan administration. First, as described above, it changes how benefits are calculated and paid, requiring new methods for doing so. Changing the way benefits are calculated and paid interferes with plan administration. *See Egelhoff v. Egelhoff*, 532 U.S. 141, 148 (2001). Therefore, ERISA preempts laws that do so.

Second, the Network Restrictions and Specialty Drug Rule also curtail PBMs' abilities to differentiate their networks. These provisions will destroy preferred networks, prevent PBMs from ensuring that beneficiaries are treated by qualified pharmacists, impair disease management programs, and artificially increase retail pharmacies' negotiating leverage. Together, these provisions shrink the menu of benefits PBMs can offer plans and beneficiaries, and prevent plans from containing certain terms. Thus, they "regulat[e] the type of benefits or terms of ERISA plans," *David P. Coldesina*, 407 F.3d at 1136, and are preempted.

2. Medicare Part D Preempts the Act and the Regulations

Medicare Part D provides government sponsored prescription drug benefits for Medicare beneficiaries, including people age 65 and older and certain others with disabilities. Pub. L. No. 108-173 §101, 117 Stat. 2066, 2071-2152 (Dec. 8, 2003) (the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 or the "MMA"). In creating Medicare Part D, Congress established a comprehensive statutory and regulatory scheme that balances cost to the government and beneficiaries with access via "a market-based model under which marketplace competition ensures that enrollees receive low prices for prescription drugs." 70 Fed. Reg. 4194, 4244.

a. Congress Intended to Broadly Preempt State Interference with Part D Plans

Medicare Part D's preemption provision is broad in order to further Congress's goal to permit marketplace competition to achieve low prices for beneficiaries:

> "The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Part D plans] which are offered by [Part D sponsors] under this part."

42 U.S.C. §1395w-26(b)(3) (emphasis added). 42 U.S.C. § 1395w-112(g) (incorporating the Medicare Part C preemption provision into Medicare Part D).

While no appellate Court has yet considered the full breadth of Medicare preemption,[6] this Court need not determine the boundaries of Medicare Part D

[6] In its brief to the U.S. Court of Appeals for the Eighth Circuit in *PCMA v. Tufte*, No. 18-2926, PCMA has asked the Eighth Circuit to confirm that Medicare Part D preempts state laws that act with respect to Medicare Part D plans, regardless of the presence of a related federal standard. The Eighth Circuit has yet to decide that case.

preemption to decide this case. Appellate courts that have considered Part D preemption have found preemption when "(1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established 'standards' in the area regulated by the state law; and (2) the state law acts 'with respect to those standards.'" *Rutledge,* 891 F.3d at 1113[7]; *see also Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1148 n. 20 (9th Cir. 2010) (state law claims preempted where they acted with respect to Medicare standards).[8] "Conflict between the state law and the federal standard is unnecessary." *Rutledge,* 891 at 1113. If the state law in question merely acts with respect to the standard, it is preempted. *See Arcadian Health Plan, Inc. v. Korfman*, 2010 U.S. Dist. LEXIS 133003 (D. Maine Dec. 14, 2010) (state may not avoid preemption through "indirect" regulation "with respect to areas addressed by the federal [Medicare] standards," or by "artful legislating to ignore the federal standards").

b. The Act Acts With Respect to Medicare Part D Standards

The Act acts with respect to at least eight different Medicare Part D standards. In each of these instances, the Act includes requirements for Part D plans in areas where Congress and CMS have already spoken. Further, while not necessary for purposes of preemption, the Act conflicts with several of these federal standards.

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[7] Arkansas's petition for certiorari did not ask the Supreme Court to review the Eighth Circuit's holding that the Arkansas statute was preempted by Medicare Part D.
[8] A standard within the meaning of the preemption provision is either a statutory provision or a duly promulgated and published regulation. *Uhm*, 620 F.3d at 1148 n. 20.

- Medicare Part D has a Preferred Pharmacy Network Standard, which expressly permits the use of preferred pharmacy networks. 42 C.F.R. §423.120(a)(9). The Network Restrictions act with respect to this standard by restricting the use of preferred pharmacy networks.
- Medicare Part D has a Pharmacy Access Standard that dictates the geographic dispersion of brick-and-mortar pharmacies in a Part D Plan's pharmacy network. 42 C.F.R. §423.120(a). The Retail-Only Pharmacy Access Standard acts with respect to this standard by adding requirements to those set by CMS.[9]
- Medicare Part D has its own Any Willing Provider Standard for standard, non-preferred networks only. 42 C.F.R. §423.120(a)(8). By requiring a PBM to permit a pharmacy into its more limited preferred pharmacy network, the Act's Any Willing Provider Requirement conflicts with that standard.
- Part D beneficiaries must have access to prices negotiated between the PBM and the network pharmacy. 42 U.S.C. §1395w-102(d) (the Negotiated Price Standard); 42 C.F.R. §§ 423.100 & 423.104(g). The Affiliated Pharmacy Price Match and the Post-Sale Price Reduction Prohibition replace the negotiated price between the PBM and the pharmacy with either the price paid by a PBM to an affiliated pharmacy or the

[9] In addition, CMS has articulated when the federal Pharmacy Access Standard does not apply to specialty drugs. CMS Medicare Prescription Drug Benefit Manual, ch. 5, 50.3. As such, the Specialty Drug Rule and the Beneficiary Direction Provisions also act with respect to this standard.

price originally paid at the point of sale. *See Rutledge*, 891 F.3d at 1113 (MMA preempted state law that "effectively replaces the negotiated […] price").

- Medicare Part D standards ensure that the amount a Part D sponsor pays a pharmacy is the product of a market-based negotiation free from government interference. *See* 42 U.S.C. §1395w-111(i) (non-interference clause); 42 U.S.C. §1395w-26(b)(3) (pre-emption of state law). The Service Fee Prohibition acts with respect to these standards because it restricts this negotiation by prohibiting the use of any price structure in which a pharmacy pays a fee related to the adjudication of a claim.
- Medicare Part D requires Part D sponsors to assert that network providers are in compliance with state pharmacy laws. 42 C.F.R. §423.153(c) (the Quality Assurance Standard). By restricting how a PBM may respond when a network pharmacy employs a suspended pharmacist, the Pharmacy Termination Prohibition and the Terminated Pharmacy Payment Provision act with respect to this standard.
- The Part D sponsor "retains the right to approve, suspend, or terminate" a PBM's selection of network pharmacies. 42 C.F.R. §423.505(i)(5). The Health Insurer Monitoring Requirement and the Contract Approval Rule act with the respect to the federal standards by adding new monitoring requirements for Part D sponsors.
- Medicare has a Communications and Marketing Materials Standard that regulates which pharmacies a PBM may include on ID cards and other materials. 42 C.F.R. §423.2262. The Promotional Materials Provision acts with respect to this standard by regulating the content of the same materials.

3. The Regulations Violate the APA

The Oklahoma Administrative Procedure Act places the burden on the state to show "that the rule is consistent with any statute authorizing or controlling its issuance and does not exceed statutory authority." 75 Okl. St. § 306(C)(2). Oklahoma courts generally do not grant deference to agencies' statutory interpretation: they "decide questions of law and do not defer to agency interpretation of the Constitution or the statutes." *Metcalf v. Okla. Bd. of Med. Licensure & Supervision*, 848 P.2d 48, 50 (Okla. Ct. Civ. App. 1992) (overruled in part on other grounds, 2000 OK 45 (2000)).

The Promotional Materials Rule is inconsistent with the Promotional Materials Prohibition because it copies part of the Prohibition but leaves out a significant qualifying clause: "participating in the preferred and nonpreferred pharmacy and health networks." *Compare* 36 O.S. §6961(D) *with* Okla. Admin. Code § 365:25-29-7.1(a)(3). The Contract Approval Rule appears to require each health insurer that contracts with a PBM to approve every contract a PBM enters into. But the statute requires health insurers merely to "monitor" the activities of those with which they contract and "ensur[e] that the requirements of this act are met." 36 O.S. 6963(B). The Specialty Drugs Rule arbitrarily applies the Act to specialty drugs even though specialty drug management differs greatly from standard drug management. Caldwell ¶ 45. The regulations justify this application because, they say, "[t]he act draws no distinction between regular or specialty drugs." Okla. Admin. Code 365:25-29-7.1. This is false. One provision does draw that distinction. *See* 36 O.S. 6961(C).

B. The Act and Regulations Irreparably Harm PCMA's Members

"An irreparable harm requirement is met if a plaintiff demonstrates a significant risk that he or she will experience harm that cannot be compensated after the fact by monetary damages." *Greater Yellowstone Coalition v. Flowers*, 321 F.3d 1250, 1258 (10th Cir. 2003) (internal quotation marks omitted) (emphasis removed). This harm must not be speculative. *See id*. Enforcing the Act and Regulations would irreparably harm PBMs because it would subject them to multiple regulators, force them to restructure their business models, and cause them unrecoverable financial and administrative costs.

Being subject to multiple regulators in violation of the Supremacy Clause has been held to cause irreparable harm. *See Trans World Airlines v. Mattox*, 897 F.2d 773, 783-84 (5th Cir. 1990) (state law regulating the airline industry that was likely preempted caused irreparable harm). This is especially so given the breadth of ERISA and Medicare Part D preemption. Enforcement causes PBMs irreparable harm for that reason alone. The Act irreparably harms PBMs in other ways as well.

1. Enforcing the Act and Regulations Will Force PBMs to Fundamentally Restructure Their Business Models

Where a law requires an industry to change its business model, those changes can constitute irreparable harm. Although the Tenth Circuit has not addressed the issue, courts in other jurisdictions have found irreparable harm when complying with a state law would force the plaintiff to change its business model. *See, e.g., Cal. Trucking Ass'n v. Becerra*, 2020 U.S. Dist. LEXIS 7707, at *31-32 (S.D. Cal. Jan. 6, 2020) (trucking

companies irreparably harmed by law that would reclassify drivers from independent contractors to employees because law would require them to "significantly restructure their business model"); *Teladoc, Inc. v. Tex. Med. Bd*., 112 F. Supp. 3d 529 (W.D. Tex. 2015) (law prohibiting telehealth services without preliminary in-person visit irreparably harms telehealth physicians by causing "destruction of a business model").

Enforcement will require PBMs to change their core services in Oklahoma. PBMs influence price and quality by offering wide arrays of networks and services, including preferred networks and disease management services. They have also developed innovative propriety methods, which apply nationwide, for determining drug pricing based on the existence of these networks. Enforcement would require PBMs to fundamentally change how they control and calculate prices. Specifically:

- The Network Restrictions and Specialty Drug Rule will prevent PBMs from offering preferred networks and disease management services. Caldwell ¶¶ 55, 62.
- The Claims Processing Provisions inhibit PBMs and pharmacies from agreeing to funding arrangements where pharmacies pay PBMs administrative fees. Conlin ¶ 41; Correia ¶ 47; Johnson ¶ 34; Stacy. ¶ 25.
- The Affiliated Pharmacy Price Match requires PBMs that do not calculate pricing on a unit by unit basis to start doing so. Caldwell ¶ 59.
- The Pharmacy Termination Prohibition prevents PBMs from guaranteeing beneficiaries treatment by pharmacists who provide high quality services. *Id*. ¶ 63.

2. Enforcement Will Cause PBMs to Suffer Unrecoverable Financial Harm and Incur Unrecoverable Administrative Costs

Financial harm is irreparable when sovereign immunity prevents the plaintiff from recovering money damages from the state. *See Crowe & Dunlevy, P.C. v. Stidham*, 640 F.3d 1140, 1157 (10th Cir. 2011). The amount of the financial loss does not matter; what matters is simply that it is irreparable. *See Wilson v. Amoco Corp*., 989 F. Supp. 1159, 1177 (D. Wyo. 1998). Unrecoverable administrative costs of compliance also support a finding of irreparable harm. *See Chamber of Commerce of the United States v. Edmondson*, 594 F.3d 742, 756, 770-71 (10th Cir. 2010). PBMs will be harmed financially and administratively in a number of ways:

- PBMs will have to renegotiate contracts with pharmacies or PSAOs to comply with the Act. Conlin ¶ 48; Correia ¶ 44; Johnson ¶ 39; Stacy ¶ 11. Negotiating PBM-pharmacy contracts can take up to a year, and each negotiation has significant costs.[10] Caldwell ¶ 56.
- The Act's changes to networks and payment terms will also require PBMs to renegotiate health plan contracts. Conlin ¶ 30; Johnson ¶¶ 39, 40; Stacy ¶ 11; Correia ¶ 44.

[10] For example, Prime Therapeutics LLC estimates that it will have to renegotiate over 900 agreements. Each such negotiation could take up to 40 hours to complete. Conlin ¶ 31.

- The Promotional Material Provision will require PBMs to alter every piece of written material that refers to a pharmacy, hospital, or other health provider. Caldwell ¶ 67.
- The Service Fee Prohibition eliminates a revenue source from PBMs, ranging from $35,000 to $200,000 per month depending on the PBM. Stacy ¶ 25; Correia ¶ 47; Conlin ¶ 41.

3. Enforcement Is Especially Harmful Given COVID-19

PBMs, like all businesses, are affected by COVID-19. They have suffered from an abrupt transition to remote work, the elimination of childcare and elder care for employees, resignations, and FMLA requests. Conlin ¶ 21; Johnson ¶¶ 21-22; Stacy ¶ 28; Correia ¶ 26. Many of these problems will persist when work restrictions are relaxed. Social distancing will remain a priority, limiting both employees' opportunities to return to the office and available care for family members.

Moreover, PBMs and health plans are at the front lines of responding to COVID-19. PBMs have done much in a short period of time to implement public health-conscious measures to ensure prescription drug accessibility during the crisis.

Given PBMs' internal structures, the very employees responding to the COVID-19 crisis would be tasked with complying with the Act. Caldwell ¶ 8. PBMs cannot do both without being overwhelmed in an unprecedented manner. *Id*. Thus, they will risk inhibiting their responses to the public health crisis in order to comply with this law. This harm is irreparable and unnecessary.

C. The Balance of Hardships Favors a Preliminary Injunction

Enforcement would irreparably harm PCMA's members, while maintaining the status quo would cause the defendants no harm at all. First, as a legal matter, defendants have no interest in enforcing preempted state laws like the Act. *See Edmondson*, 594 F.3d at 771. Second, defendants' repeated decisions to continue to stay enforcement – when the Act came into effect, between the start of the COVID-19 outbreak and the postponement of the *Rutledge* oral argument, and during the pendency of this motion – belies any suggestion that enforcement is necessary to protect a pressing state interest. The balance of hardships thus tilts in PCMA's favor.

D. The Public Interest Favors a Preliminary Injunction

Enforcing the Act and Regulations would hinder PBMs' response to COVID-19 and lower the quality and cost of services PBMs can provide beneficiaries. It thus contravenes the public interest.

1. Enforcement Would Prevent PBMs from Responding Effectively to the COVID-19 Crisis

Given their centrality to prescription drug distribution, PBMs are integral to the collective response to the COVID-19 crisis. PBMs have facilitated COVID-19 treatment, maintained access to non-COVID-19-related health care, and facilitated CDC-recommended practices like social distancing, through the following time-consuming measures, each of which applies to beneficiaries filling prescriptions in Oklahoma:

- Allowed access to out-of-network pharmacies where access to in-network pharmacies may be limited.
- Taken several measures to minimize face-to-face interactions among beneficiaries and pharmacies, including by facilitating mail-order service.
- Monitored supply chains to ensure beneficiaries' uninterrupted access to prescription drugs in the face of drug hoarding.
- Added quantity limits to certain in-demand drugs to prevent shortages. Conlin ¶¶ 19-20; Correia ¶¶ 23-24; Stacy ¶ 27; Johnson ¶¶ 19-20.

PBMs are facing workforce challenges caused by the pandemic, and the same employees who are responding to COVID-19 would also be responsible for complying with the Act and Regulations. This double duty could impede PBMs' response to COVID-19, to the detriment of public health. In addition, the Act's increased costs to beneficiaries would be magnified given the economic consequences of the pandemic.

Enforcement now is unnecessary. Contrary to what the defendants have suggested in other filings, none of the Act's provisions will enhance the response by PBMs or pharmacies to the pandemic. Indeed, the OID has released and amended a bulletin recommending PBMs take measures like those described above.[11] This bulletin, unlike the Act and Regulations, is tailored to the pandemic.

[11] Oklahoma Insurance Department, "LH BULLETIN NO. 2020-02 (AMENDED)" (Apr. 29, 2020), https://www.oid.ok.gov/lh-bulletin-no-2020-02-amended/ (last accessed May 13, 2020).

2. Enforcement in General Contravenes the Public Interest

Even apart from COVID-19, enforcement would harm the public because of the Act's and Regulations' adverse impacts on beneficiaries, including the increased prescription drug costs (particularly for beneficiaries who have cost-sharing or deductible obligations), the reduction in quality assurance measures, and the impairment to disease management programs.

CONCLUSION

For the foregoing reasons, the court should grant PCMA's motion for preliminary injunction.

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Dated: May 13, 2020

CERTIFICATE OF SERVICE

I hereby certify that on May 13, 2020, I electronically transmitted the attached document to the Clerk of the Court using the Electronic Case Filing System for filing. Based on the records currently on file in this case, the Clerk will transmit a Notice of Electronic Filing to those registered participants of the ECF System.

/s/ Stephen Stich
Stephen Stich